



Safety of primary anastomosis following emergency left sided colorectal resection

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Safety of primary anastomosis following emergency left sided colorectal resection: An international, multi-centre prospective audit

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Abstract

Introduction: Some evidence suggests that primary anastomosis following left sided colorectal resection in the emergency setting may be safe in selected patients, and confer favourable outcomes to permanent enterostomy. The aim of this study was to compare the major postoperative complication rate in patients undergoing end stoma versus primary anastomosis following emergency left sided colorectal resection.

Methods: A pre-planned analysis of the European Society of Coloproctology 2017 audit. Adult patients (>16 years) who underwent emergency (unplanned, within 24 hours of hospital admission) left sided colonic or rectal resection were included. The primary endpoint was the 30-day major complication rate (Clavien-Dindo grade 3 to 5).

Results: From 591 patients, 455 (77%) received an end stoma, 103 a primary anastomosis (17%) and 33 primary anastomosis with defunctioning stoma (6%). In multivariable models, anastomosis was associated with a similar major complication rate to end stoma (adjusted odds ratio for end stoma 1.52, 95%CI 0.83-2.79. $p=0.173$). Although a defunctioning stoma was not associated with reduced anastomotic leak (12% defunctioned [4/33] versus 13% not defunctioned [13/97], adjusted odds ratio 2.19, 95%CI 0.43-11.02, $p=0.343$), it was associated with less severe complications (75% [3/4] with defunctioning stoma, 86.7% anastomosis only [13/15]), a lower mortality rate (0% [0/4] versus 20% [3/15]), and fewer reoperations (50% [2/4] versus 73% [11/15]) when a leak did occur.

Conclusions: Primary anastomosis in selected patients appears safe after left sided emergency colorectal resection. A defunctioning stoma might mitigate against risk of subsequent complications.

What this paper adds

Anastomosis after emergency left sided colorectal resection is performed in up to one in five patients. In these highly selected patients, this study suggests that it is safe practice. A defunctioning stoma may mitigate against risk if an anastomotic leak subsequently occurs.

Introduction

In patients undergoing emergency left sided colorectal surgery, resection with end colostomy is a commonly described procedure. Concerns about the safety of any anastomosis in the emergency setting are particularly high in the presence of contamination or an unstable patient [1, 2]. Although a stoma avoids the risk of anastomotic leak, it carries with its own morbidity and mortality profile (27-55% and 4-27% respectively) [2]. For patients that undergo end stoma formation, the reversal rate is as low as 44% in published series [3], with a significant impact on long-term quality of life and a risk of stoma-related complications.

Many studies have evaluated primary anastomosis in the emergency setting with generally favourable results. Multiple single-centre, retrospective, observational studies have demonstrated that anastomosis can be safely performed in selected patients within the emergency setting, even in presence of peritonitis [4-6]. However, ~~it remains fairly uncommon practice and often only undertaken by more specialised or experienced colorectal surgeons.~~ The number of supporting randomised trials in the literature is low and those that exist are mainly related to peritonitis secondary to perforated diverticulitis, with primary anastomosis often only undertaken by specialised colorectal surgeons [4, 7, 8].

Decision-making about whether to create a primary anastomosis in selected, stable patients in an emergency setting remains a challenge for the individual surgeon. The decision must take into account patient comorbidities, intraoperative findings, underlying colorectal pathology, clinical status of the patient and expertise of the surgeon [9]. The aim of this ~~multi-centre international study was to provide-examine whether more evidence to guide whether~~ current decision-making in real-world settings supports primary anastomosis as a safe technique in selected patients after emergency left sided colorectal resection.

Methods

Protocol and centres

This prospective, observational, multi-centre study was conducted in line with a pre-specified protocol (<http://www.escp.eu.com/research/cohort-studies>). All participating centres were responsible for compliance to local approval requirements for ethics approval or indemnity as required. In the UK, the National Research Ethics Service tool recommended that this project was not classified as research, and the protocol was registered as clinical audit in all participating centres. Any unit performing gastrointestinal surgery was eligible to register to enter patients into the study. No minimum case volume, or centre-specific limitations were applied. The study protocol was disseminated to registered members of the European Society of Coloproctology (ESCP), and through national surgical or colorectal societies.. This study represents planned analysis of the European Society of Coloproctology 2017 audit database.

Patient eligibility

Adult patients (>16 years) undergoing left side colectomy or rectal resection, via any operative approach in emergency ~~(within 24 hours)~~ settings (within 24 hours of hospital admission) were extracted from the main audit database. Any indication for surgery (benign or malignant) were eligible. Patients undergoing planned elective surgery were excluded, as were those undergoing left colorectal resection as part of a more extensive resection (e.g. subtotal colectomy, panproctocolectomy).

Data capture

Consecutive sampling was performed of eligible patients over an 8-week study period in each included centre. Local investigators commenced data collection on any date between the 1 January 2017 and 15 March 2017, with the last eligible patient being enrolled on 10 May 2017. Small teams of up to five surgeons or surgical trainees worked together to collect prospective

data on all eligible patients at each centre. Quality assurance was provided by at least one consultant or attending-level surgeon. Data was recorded contemporaneously and stored on a secure, user-encrypted online platform (REDCap) without using patient identifiable information. Centres were asked to validate that all eligible patients during the study period had been entered, and to attain >95% completeness of data field entry prior to final submission.

Outcome measure

The primary outcome measure was the 30-day postoperative major complication rate other, defined as Clavien-Dindo classification grade 3 to 5 (other than anastomotic leak including reoperation, reintervention, unplanned admission to critical care, organ support requirement or death). The secondary outcome measure was anastomotic leak, pre-defined as either i) gross anastomotic leakage proven radiologically or clinically, or ii) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on post-operative imaging.

Statistical analysis

This report has been prepared in accordance to guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies [10]. Patient, disease and operative characteristics were compared using Student's t-test for normal, continuous data, Mann-Whitney U test for non-normal continuous data or Chi-squared test for categorical data. To test the association between the outcome measures and the main explanatory variables of interest (expedited versus emergency, end stoma versus primary anastomosis), a mixed-effects logistic regression model was fitted. Clinically plausible patient, disease and operation-specific factors were entered into the model for risk-adjustment, treated as fixed effects. These were defined *a priori* within the study protocol, and included irrespective of their significance on univariate analysis. Hospitals were entered into the model as a random-effect, to adjust for hospital-level variation in outcome. Effect estimates are presented as odds

ratios (OR) with 95% confidence intervals (95% CI) and two-tailed p-values. Model discrimination was ~~tested~~ quantified using C-statistic, or, ~~analogous to~~ the area under the receiver operating characteristic curve ~~curve~~ (AUC) of the model. An alpha level of 0.05 was used throughout. Data analysis was undertaken using R Studio V3.1.1 (R Foundation, Boston, USA).

Results

Patients

This study included 591 patients undergoing emergency surgery from 43 countries [\(Figure 1\)](#). The mean age of patients was 67.4 years (ranging from 18-96). 51.8% were male and 57.4% had a high anaesthetic risk class (ASA 3-5). Differences in demographics between patients with anastomosis and end stoma are shown in Table 1. Primary anastomosis was performed in 136 patients (23%) with 33 of these patients receiving a defunctioning stoma. This stoma was a loop ileostomy in 84.8% (28/33), an end/double-barreled ileostomy in 6.1% (2/33) and a loop colostomy in 3.0% (3/33). [30.1% \(178/591\) of included operations were done for malignancy, with end stoma being most common operative strategy \(73.0%, 130/178\). Of these, 20.2% were undergoing neoadjuvant therapy prior to their presentation for emergency surgery \(short course radiotherapy, 7/36; long course chemoradiotherapy, 18/36; chemotherapy only: 11/36\). Primary anastomosis with or without defunctioning stoma was performed less frequently than end stoma in disease affecting the rectum \(14.9% and 7.2% versus 77.9% respectively\).](#) -An anastomosis was attempted in 27% (87/326) of patients operated upon by a colorectal surgeon and 18% (49/265) by a general surgeon ($p=0.059$, [table 4Figure 2](#)).

Major complications (Clavien-Dindo 3 to 5)

Results of analysis for factors associated with the occurrence of major complications are shown in Table [23](#). An end stoma was significantly associated with increased major postoperative complications ~~at upon the~~ univariable analysis (OR 1.98 95% CI 1.17–3.54, $p=0.015$), [but this association was not seen following risk adjustment \(adjusted odds ratio for end stoma in mixed effects model 1.52, 95%CI 0.83-2.79, \$p=0.173\$ \).](#) In the multilevel model significant predictors for major complications were high ASA risk (grade 3-5) (OR 2.54, 95% CI 1.59–4.07, $p<0.001$), ~~overweight or obese~~ [\(OR 1.88, 95% CI 1.17-3, \$p=0.009\$ \)](#) and male gender (OR 1.66, 95% CI 1.10–2.51, $p=0.016$). [Overweight BMI was associated with a lower major complication rate](#)

than a normal BMI (OR 0.53, 95% CI 0.33-0.85, $p=0.009$), however the location of resection (involving rectum or colonic only) demonstrated no association. Anastomosis was associated with a similar major complication rate to end stoma (adjusted odds ratio for end stoma 1.52, 95%CI 0.83-2.79, $p=0.173$). The model demonstrated fair discrimination (AUC: 0.71).

Anastomotic Leak

Unadjusted outcomes according the anastomotic strategy, stratified by presence of leak, are shown in Table 3. Although a defunctioning stoma was not associated with reduced anastomotic leak (12% defunctioned [4/33] versus 13% not defunctioned [13/97], adjusted odds ratio 2.19, 95%CI 0.43-11.02, $p=0.343$), it was associated with fewer major complications (75% [3/4] with defunctioning stoma, 86.7% anastomosis only [13/15]), lower mortality (0% [0/4] versus 20% [3/15]), and reoperation 50% [2/4] versus 73% [11/15]) when a leak did occur (Figure 3). The minor complication rate was similar between groups where the anastomosis successfully healed without leak (41.4% defunctioned [12/27] versus 34.1% not defunctioned [30/88]) and where an end stoma was formed (32.7% [149/455]). There was no difference in the anastomotic leak rate between anastomosis with and without defunctioning stoma ($p=0.343$). On the univariable analysis, age over 70 years old (OR 10, 95% CI 1.61-100, $p=0.037$) and (Table 4) previous history of IHD/CVA (OR 5.06, 95% CI 1.50-16.27, $p=0.007$) were associated with an increased risk of leak, whilst being of middle age was protective (age 55 to 70 years old; OR 0.10, 95% CI 1.61-100, $p=0.037$). When a multilevel model was fitted (Figure 4), a significant association was found with age over than 70 years old (OR 20, 95% CI 0.00-1.51, $p=0.023$) a history of diabetes also conveyed an increased risk of leak (OR 8.56, 95% CI 1.16-63.38, $p=0.035$). The model demonstrated good discrimination (AUC: 0.87).

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Discussion

This study showed that primary anastomosis was performed in up to one in five patients and appears safe in this highly selected group after emergency emergency left sided colorectal resection (unplanned, within 24 hours of hospital admission). A defunctioning stoma was only used in 24% of patients with a primary anastomosis. The exploratory findings of this study, limited by small numbers, suggested that a defunctioning stoma may mitigate against risk if an anastomotic leak occurs. Other patient-related risk characteristics (male gender, high ASA class grade and overweight or obese BMI) and an open approach were identified as independent risk factors for major postoperative complications. Furthermore, young and -elderly age and or a history of diabetes were shown as risk factors for anastomotic leak in emergency procedures.

Previously, the simple formation of an end colostomy after resection of the pathology (ubiquitously known as a 'Hartmann's procedure') has been advocated as the gold standard treatment in emergency left colonic resection, to eliminate risk of anastomotic leak [11-13]. In the last fifteen years, several studies have questioned this strategy [14, 15]. A primary anastomosis is not only feasible, it may even be associated with better postoperative outcomes, both in terms of complications and mortality [16, 17]. Given that more than 40 % of temporary stomas become permanent, selecting patients correctly for a primary anastomosis is attractive [18-20]. In addition, Hartmann reversal can be a technically demanding operation resulting in further morbidity and mortality [21]. These findings support a recent consensus statements and prospective multi-centre randomized trials that suggest primary anastomosis with proximal diversion as an optimal strategy for sigmoid diverticulitis in selected patients with Hinchey 3 or 4 disease [4, 22, 23]. This current study gives credence to the current situation and confirms that surgeons are making appropriate decisions on a case-by-case level, thereby

effectively stratifying patients for primary anastomosis or end stoma. It is known that a defunctioning stoma in elective surgery has utility in mitigating the clinical impact of anastomotic leak [24, 25]. Loop ileostomies and their closure are not complication-free and several studies have shown that temporary loop ileostomies can become permanent in up to 25% of patients [24-28]. However this study comparably suggests that a defunctioning stoma may mitigate some risk when a leak occurs. This must be interpreted with caution since numbers in this study were low; for example, only four patients with an anastomosis and defunctioning stoma suffered a leak.

There were slightly more primary anastomotic attempts by colorectal versus general surgeons in this study. Even though there is no homogenous definition of colorectal surgeon internationally, results of multiple studies confirm the importance of colorectal specialisation in the emergency setting [29, 30]. An individual surgeon's personality and their response to perceived operative risk may also influence choice of anastomotic strategy [31]. –Further research is needed to determine whether the grade and surgical specialism of the operating (or senior) surgeon, and specialisation and experience of included centres affect both the decision ~~to~~ for anastomosis and the subsequent clinical outcome.

There are inherent limitations to the 'snapshot' observational study reported here in this study which we have attempted to overcome in the study design, statistical analysis and interpretation. There is an obvious selection bias in this study, although we planned the analysis around this *a priori*. We aimed to analyse safety of current practice; this study showed that end stoma was more frequently used in older patients, with poor general status, in smokers, and in those with arteriopathy and benign disease. However this paper defines outcomes in the highly selected group of patients undergoing anastomosis, and thus supports surgical decision making in specific cases, rather than in recommending a general change in approach. The low numbers

of anastomotic leak and major complication within secondary analyses of the subgroup undergoing anastomosis (<25% of included patients) makes estimation of effect sizes inaccurate here (reflected by broad confidence intervals). Therefore, this should be seen as exploratory only; the analysis would likely be underpowered to detect a small to moderate effect size. We are also unable to comment on the appropriateness of decision making and have not collected detailed information on parameters that may effect this (for example: contamination (Mannheim Peritonitis Index [32]), previous surgery, intraoperative physiological instability).

Most of the literature available on this topic is based on retrospective or single centres data which lacks sufficient detail to allow case-mix adjustment in multivariable models. This study therefore adds to the literature in providing a contemporary perspective using a prospective international observational study design, with a pre-specified protocol and analysis plan. In addition, the variety of centers included (in terms of number of patients, facilities and different technologies available) in this study delivers a realistic picture of the current management of emergency left colorectal resections, avoiding-reducing selection bias and increasing the external validity of the findings. The different countries and even continents involved ensured the result's validity resolving the demographic differences in diverticulitis and cancer across countries. Finally, the study is limited by short-term follow up to 30 days only; we have not collected data on stoma reversal rates, quality of life or stoma-related complications following surgery. An alternative complication categorisation system such as the Comprehensive Complications Index [33] may also give increased fidelity in comparisons between intermediate term outcomes. Further evaluation of these important parameters following emergency left sided colorectal surgery is warranted.

The data from this study supports current international practice of primary anastomosis following emergency left sided colorectal resection in a highly selected group of patients, demonstrating satisfactory safety and an acceptable morbidity profile. Where an anastomosis is formed, a

defunctioning stoma does not appear to reduce the risk of leak, but may mitigate the severity of resultant complications.

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